K082250

OCT 1 0 2008

Auragen™ Cortical Surface Electrodes
510(k) SUMMARY

Submitter's name and address:

Integra NeuroSciences Implants SA
2905 Route des Dolines
06921 Sophia Antipolis Cedex, France

Contact person and telephone number:

Anne Bigeard, Regulatory Affairs Manager
Telephone: +33 (0)4 93 95 5667
Facsimile: +33 (0)4 93 65 4030

Date summary was prepared:

September 22, 2008

Name of the device:

Proprietary Name:	Cortical Surface Epilepsy Electrodes
Common Name:	Cortical Electrodes
Classification Name:	Cortical Electrodes, GYC

Substantial Equivalence:

The modified cortical surface electrodes are substantially equivalent to the cortical surface electrodes cleared by the FDA under 510(k) (K926424). The design, intended use, materials of composition, functional/performance specifications, manufacturing process are equivalent to the previously cleared cortical surface electrodes.

Intended use:

The cortical surface electrodes are intended for the intraoperative recording of EEG signals at the cortical surface of the brain.

Device Description:

The cortical surface electrodes are designed for intraoperative monitoring of cortical electrical activity in order to define the location of epileptogenic foci. They are placed on the exposed cortical surface or inserted into the subdural space to contact the cortical surface. Cortical electrodes vary in size according to the number of contacts. The type of cortical electrode used is dependent on the procedure and the size of area being tested. The Auragen Cortical Electrodes are available with platinum/iridium contacts, with 4 to 64 contacts. The electrodes are connected to Integra recording cables themselves connected to the hospital EEG recording equipment.

Safety and Effectiveness:

An array of cortical electrodes were subjected to MRI testing, which included radio frequency induced heating, magnetically induced displacement force and torque. MR imaging artifacts were assessed and the artifacts that appeared were shown as localized signal voids that were considered small in size in relation to the size and shape of the product. Results of the testing supports a "MR

Conditional" labeling claim as defined in *ASTM F 2503-05, Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment*. The cortical electrodes are provided sterile and are non-pyrogenic. The cortical electrodes have been tested for dimensional, physical and electrical performance and meet the defined requirements of the products specification.

Conclusion:

The modified cortical electrodes defined in this submission are substantially equivalent to the unmodified cortical electrodes cleared by the FDA under 510(k) (K926424). The modifications do not affect the intended use, the fundamental scientific technology of the device, and do not raise new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Integra Neurosciences
% Integra Lifesciences Corporation
Mr. Jon Caparotta
Director, Regulatory Affairs
311 Enterprise Drive
Plainsboro, New Jersey 08536

OCT 10 2008

Re: K082250
Trade/Device Name: Auragen Cortical Surface Electrodes
Regulation Number: 21 CFR 882.1310
Regulation Name: Cortical Electrode
Regulatory Class: Class II
Product Code: GYC
Dated: September 22, 2008
Received: September 23, 2008

Dear Mr. Caparotta:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known):

Device Name: Auragen™ Strip and Grid Electrodes

Indications For Use:

The Auragen™ Cortical Surface Electrodes are intended for the intraoperative recording of EEG signals at the cortical surface of the brain.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

MD

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number k082250